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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,178	02/12/2002	David J. Eyre	7475-69889	5007

23643 7590 05/11/2004
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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,178	EYRE ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 18-24 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5132002, 5022003</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicants' election of specie B (a device not provided in a portable container), filed 3/22/04, is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 24 is withdrawn from consideration as being drawn to a non-elected specie.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to multi-test analysis of real-time nucleic acid amplification, whereas in contrast the elected claims are specifically directed to a device for determining the presence of a nucleic acid in a sample.

The information disclosure statements, filed 5/2/03 and 5/13/02, were considered by the Examiner.

Claims herein under examination are 18-23.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-23 are rejected under 35 U.S.C. 102(a) and 102(e)(2) as being anticipated by Schork et al. (P/N 6,291,182 B1).

Schork et al. disclose methods, software, and apparatus for determining the presence of a gene with a detectable trait in a genomic region (presence of a nucleic acid in a sample) (abstract). Schork et al. disclose using a Perkin Elmer 9600 Thermocycler to perform amplification of nucleic acids (col. 47, lines 1-6). Schork et al. disclose performing 40 cycles with 30 seconds at 95 degrees Celsius, 1 minute at 54 degrees Celsius and 30 seconds at 72 degrees Celsius (col. 47, lines 2-6) which represent rapid thermal cycling, as stated in instant claim 22. Schork et al. disclose using a fluorimeter and Picogreen (fluorescence) to determine quantities of amplification products (col. 47, lines 7-9). Schork et al. disclose the use of dideoxy terminator sequencing reactions (col. 47, lines 10-15) which represent a plurality of tests. Schork et al. disclose determination of sequences of amplification products (performing analysis routines) wherein the sequence data is evaluated using software designed to detect sites among the amplified products via different fluorescent molecules and by evaluating intensity ratios (col. 47, lines 10-28). Schork et al. disclose excluding artifacts due to background noise by comparing two DNA strands (col. 47, lines 29-34) which represents a signal-to-noise ratio test, as stated in instant claim 19. Schork et al. disclose using a variety of mathematical analysis tests, including Expectation-Maximization method (Maximum to Baseline Comparison Test) (col. 2, line 6), Wilcoxon rank test (function ordering test) (col. 2, line 62), Kolmogorov-Smirnov test (efficiency test using normal distribution) (col. 2, line 65), chi-square test (confidence interval

test) (col. 2, line 50), and nonparametric tests (Last Rise Test) (Fig. 24). Schork et al. disclose performing linkage analysis based upon establishing a correlation between transmission of genetic markers and that of a specific trait throughout generations within a family and statistical methods for determination of the likelihood that the marker and trait are segregating independently (col. 18, lines 39-64) which represents a type of Channel Consistency Test where the channel consistency is represented by the consistent flow (presence) or lack thereof of the marker and trait transmission throughout generations.

Thus, Schork et al. anticipate the limitations in claims 18-23.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

May 3, 2004

Ardin H. Marschel 5/10/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER